

Will the mirror crack?

The pharmaceutical industry must take a good look at itself if it is to face the challenges of the next seven years. This is the wake-up call described in PricewaterhouseCoopers (PWC) report entitled *Pharma 2005: An Industrial Revolution in R&D*.

Over the past seven years the R&D spend of the top 20 pharmaceutical companies has more than doubled. Product lifecycles have shortened dramatically: ten years' market exclusivity could be expected in the past, but now it is reduced to months. In addition, the pressure on prices through a decline in sales growth has contributed to the present hostile environment in which only the fittest companies will survive.

According to current sales forecasts, there will be just 7% per annum growth over the next seven years – well below the double-digit growth in the 1970s and 1980s – and for many companies to maintain even this level of growth, radical changes must be made in working practices. It is believed that only those companies with rich R&D pipelines, appropriate skills and the ability to transform will thrive in the new environment. Companies that fail to improve their productivity will be taken over, forced into mergers or driven into niche activities. Steve Arlington, head of pharmaceutical R&D consulting at PWC, predicts that by the year 2005 the top 20 companies will become the top 13. He says, 'the next seven years will see a revolution in the way R&D is performed. Those companies that fail to restructure their R&D process, track what they are doing, implement the right IT strategies and put the right skills in place will not survive in their current form'.

Return on shares threatened

The industry has generated outstanding total shareholder returns (TSR – capital growth plus dividends) over the past five

years (average for top 20 companies = 29% and overall = 22%). This is unsustainable with the current business model.

The report claims that for the top 20 companies to achieve the 7% per annum sales growth in line with industry forecasts, they will each need to generate an extra \$28.9 billion in sales from new products between now and 2005. This will mean producing 24–34 new drugs each earning \$1–1.45 billion, which is a 4–6-fold increase on current production.

Assuming that R&D costs rise in line with past performance at 10.8% per annum and that revenues per drug launched average \$265 million per year (the industry norm), then at a cost of \$350 million to develop an approved drug the TSR will drop to ~10% a year. But R&D costs per drug are probably higher: at \$500 million per drug the TSR will plummet to uncompetitive levels.

The answer according to PWC is to slash the R&D costs for the 90% of drugs that bring in <\$180 million per year to just \$280 million – a saving of 20–44% on costs of \$350–500 million.

Changing shape of business

New science and technologies will provide many opportunities for expansion in the future. Genomics could provide up to 25,000 new molecular targets – even if only 25% of these prove to have therapeutic value, it would still represent a 14-fold increase on the number of targets the industry has explored to date. Genomics will also provide a means to link genetics to disease, thus it will be possible to predict who is at risk from which diseases – this will open up markets for prediction, prevention and follow-up treatments. The changing demographic profile and higher lifestyle expectations will also create a demand for treating age-related diseases and for lifestyle drugs that remedy conditions such as obesity, hair loss and erectile dysfunction.

Preclinical killing fields

If the industry is to meet the challenges and make the most of the opportunities it must either be more selective at an earlier stage in the R&D process or alter the way in which R&D is performed.

Combinatorial chemistry and HTS have already increased pressure further down the R&D pipeline, but when genomics fulfills its potential these pressures will increase again. Companies must avoid pushing drugs that have no commercial viability. PWC believe that emerging technologies, such as computer modeling, will provide a means to overcome these problems by providing *in silico* techniques to select the best targets and develop the best leads, such that preclinical trials will be a redundant step and drugs will move directly from test tube to man. In the future, clinical trials could be performed entirely with computers – although, the regulatory bodies may be reluctant to accept this.

As the revolution in R&D occurs, the industry will require different skills. Knowledge management will become a key issue as the enormous quantity of data must be translated into knowledge and fed back into the development chain. Also, as the public becomes better informed and has to pay more for the healthcare that governments and healthcare providers struggle to control, it will start to call some of the shots. The winning companies in the industry will be those that manage the new technologies for competitive advantage, are more ruthless in selecting the best leads and turn data into knowledge. They will reinvent their R&D processes and make affordable drugs that people want.

Copies of *Pharma 2005: An Industrial Revolution in R&D* are available from Michelle Fichtl: tel: +44 171 939 6530, fax: +44 171 939 4939, e-mail: michelle.fichtl@uk.pwcglobal.com

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